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Award Number: **W81XWH-08-2-0102**

TITLE: **Development of a PTSD Population Registry**

PRINCIPAL INVESTIGATOR: **Raymond C. Rosen, Ph.D. (Partnering PI)**

CONTRACTING ORGANIZATION:

New England Research Institutes, Inc.
Watertown, MA 02472

REPORT DATE: September 2010

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

- ✓ Approved for public release; distribution unlimited

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-09-2010	Annual	1 SEP 2009-31 AUG 2010

4. TITLE AND SUBTITLE

Development of a PTSD Population Registry

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-08-2-0102

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Raymond C. Rosen, PhD

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

New England Research
Institutes, Inc.
Watertown,
MA 02472

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and
and Material Command
Fort Detrick, Maryland
21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRMC

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for public release; distribution unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with posttraumatic stress disorder (PTSD). This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to evaluate risk factors for PTSD among combat-exposed service men and women. The pilot phase of this project was completed in January 2010. Pilot data were collected on 13 men and 14 women. 73% met criteria for PTSD. Data collection for the full sample began in May 2010. To date, 169 phase 2 participants have completed.

15. SUBJECT TERMS
Risk factors for PTSD. PTSD symptom development and VA healthcare utilization.

16. SECURITY CLASSIFICATION OF: U			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT U	**b. ABSTRACT** U	**c. THIS PAGE** U	UU	8	**19b. TELEPHONE NUMBER** *(include area code)*

Table of Contents

INTRODUCTION

The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with PTSD. This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to determine risk factors for PTSD among combat-exposed service men and women (by incorporating a combat-exposed non-PTSD group of veterans into analyses). Thus, the registry will allow an evaluation of current theoretical models of symptom development in a large sample of service men and women who utilize the VA medical system.

BODY

Initial study approval was received from OHRP in month 12 of year 1. In months 1 and 2 of year 2 sites submitted all continuing review approval materials to OHRP. Approval to begin the pilot phase was received from OHRP in month 2 of year 2. Pilot testing took place over the course of months 3 through 5. The level 1 roster of potential participants was obtained from the DC VA Medical Center in month 3. During months 3 and 4 the initial opt-out letter was mailed to the 3,000 participants on the level 1 roster. In month 5 the second opt-out letter was mailed to the 2,169 potential participants on the level 1 roster who did not respond to the initial opt-out letter. Approximately 900 letters were returned because of a bad addresses or forwarding address. A third cycle of opt-out letters was mailed to these participants after a correct address was located in CPRS. In total, 772 positive responses and 160 refusals were received. Of the original level 1 roster there were a total of 1,232 non-responders.

Pilot participants were 13 men and 14 women (n=27) who returned the initial opt-out letter. The mean age of the pilot sample was 41. Seventy-three percent of pilot participants met criteria for PTSD. Pilot testing was completed in month 5 concluding phase 1 of the project. Materials for approval to begin phase 2 were submitted to OHRP at the beginning of month 6. Additional supporting materials as well as documentation of local continuing review were submitted to OHRP in month 7. Approval to begin phase 2 was received on April 30th 2010 (month 8). Full sample data collection began in early in month 9 and is ongoing. By the end of month 11 research technicians had made at least initial contact with most of the 772 potential participants. Research technicians began making calls to the level 1 roster non-responders in month 12. To date 169 phase 2 participants have completed the project.

The study's Scientific Advisory Board met in month 10 to review changes made during pilot testing. One new research technician was research credentialed and trained in the same month. To date there have not been any problems that have impeded performance of the project.

Personnel receiving salary from this research effort are Raymond C. Rosen, Ph.D. (Partnering PI), Margaret A. Gates, Sc.D. (hired to replace Nancy Maserejian as Project Manager and Co-I), Lynn Sleeper, Ph.D. (Project Statistician and Co-I), and Blandyna Williams (Research Assistant).

KEY RESEARCH ACCOMPLISHMENTS

- Study measures and procedures were finalized and the manual of operations was completed.
- Pilot testing was completed.
- Phase 1 of the project is completed.
- Phase 2 recruitment is under way.

REPORTABLE OUTCOMES

- Keane, T.M., Rosen, R., Maserejian, N., Holowka, D.W., Rodriguez, P., Marx, B.P., Kang, H., Vasterling, J.J. Wunderle, K.B., Rodier, N.A., Sloan D.S., Friedman, M.J., Sleeper, L.A. (2009). Creation of a PTSD Registry for Veterans: Project VALOR. Poster presented at the annual meeting of the Association for Behavioral and Cognitive Therapies, New York, NY (November 19-22, 2009).

- Keane, T.M., Rosen, R., Maserejian, N., Holowka, D.W., Rodriguez, P., Marx, B.P., Kang, H., Vasterling, J.J. Wunderle, K.B., Rodier, N.A., Sloan D.S., Friedman, M.J., Sleeper, L.A. (2009). Creation of a PTSD Registry for Veterans: Project VALOR. Poster and oral presentation at the Department of Defense (DOD) Military Health Research Forum (MHRF); Kansas City, MO.

- Rosen, R.C., Keane, T.M., Marx, B.P., Maserejian, N.N., Holowka, D.W., Kang, H.K., Vasterling, J.J., Rodier, N.A., Sleeper, L.A. (2010, June). The Natural History of Combat-Related Posttraumatic Stress Disorder: Project VALOR. Poster presented at the World Congress of Behavioural and Cognitive Therapies, Boston, MA.

- Gates, M.A., Holowka, D.W., Vasterling, J.J., Sloan, D.M., Keane, T.K., Marx, B.P. & Rosen, R.C. (Submitted). Posttraumatic Stress Disorder in Veterans and Active Duty Military Personnel: State of the Science in Screening and Case Recognition. *Epidemiologic Reviews.*

- Rosen, R., Marx, B.P., Maserejian, N., Holowka, D.W., Sleeper, L., Kang, H. & Keane, T.M. (Submitted). Project VALOR: Design and Methods of a Longitudinal Registry of Posttraumatic Stress Disorder (PTSD) in Combat-Exposed Veterans in the Afghanistan and Iraqi Military Theaters of Operations. *International Journal of Methods in Psychiatric Research.*

CONCLUSION

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand the etiology and course of PTSD, how it can be identified at early stages, and the responsiveness of recent returnees to various treatment options. This knowledge will be of benefit to policy makers and current service members as well as victims of trauma in the broader community. It will include:

- Evaluation of the natural history and long-term outcomes of PTSD across treatments, treatment settings, and practitioners, using cost-efficient methods and economies of scale;
- A more accurate assessment of current theoretical models of symptom development, and
- Documentation of health resource utilization and development of a database that is an ideal resource for health services planning and policy.

Furthermore, this study will contribute:

- The formation of a potential cohort of subjects for ancillary studies, ranging from genomic influences to quality of life and psychosocial outcomes, as well as future clinical trials;
- The creation of a representative sample of PTSD OEF/OIF Veterans who use the VA medical system, available for use in epidemiologic studies, particularly for comparisons with active duty and other Veteran or civilian populations;
- Utility to clinicians, patient advocacy groups, and health policy planners;
- Publications and dissemination of the registry results to provide a representative perspective of what is achieved in actual current care settings, thereby augmenting outcomes data from clinical trials.

APPENDIX

AMENDED STATEMENT OF WORK – MAY 12, 2009

START DATE- September 1, 2008

VA Boston Healthcare System (BVARI)
Research Service (151)
150 South Huntington Avenue
Boston, MA 02130
PI: Terence M. Keane, Ph.D.

New England Research Institutes, Inc. (NERI)
9 Galen Street
Watertown MA 02472
Partnering PI: Raymond Rosen, Ph.D.

This project requires human subject participation.

Major Task (Milestone)	Timeline (Months)	BVARI	NERI
PHASE I – STUDY INITIATION			
IRB Approvals/Finalize Protocol			
Finalize Protocol; NERI/VHA IRB approvals and USAMRMC HRPO human subject protocol approval	1-11 TK	/BM	RR
Program and Test De-Identification			
Programs to de-identify VA in/outpatient electronic records database will be created	1-4 TK/BM		RR
De-Identification programs will be tested on sample data	1-6 TK/BM		RR
Design statistical analysis programs	3-6 TK/BM		RR
PHASE II – DATA COLLECTION			
Prepare Data for Abstraction			
Data on potential participants will be merged from electronic databases	11-27 TK/	BM	
Data will be de-identified	12-27 TK/	BM	
Transfer Data	26-27 TK/BM		RR
Resolve Queries			
Generate query reports that relate to the quality of the database based on pre-determined values	9-10		RR
Data cleaning and tracking	11-27		RR
Pretest telephone Interview Instrument			
The interview will be tested in a sample of 20 veterans who will not be enrolled in the study to assess burden, ease of comprehension and time to completion	12-13 TK/	BM	
Make modifications based on pre-testing	12-13 TK/BM		RR
Final interview tested to allow completion in a 40-50 minute telephone call	12-13 TK/	BM	
Develop manual of operations	10-13 TK/BM		RR

Identify Target Sample for Interview			
Identify 1200 OIF/OEF veterans with diagnosis of PTSD, 400 OIF/OEF veterans without diagnosis of PTSD and a mental health evaluation/assessment conducted post-deployment years in the VA medical records database	11-12 TK/	BM	
Conduct Interim Analyses			
Conduct interim analyses using existing PTSD Registry data	14-15		RR
Conduct Interviews			
Interviewers will be extensively trained and monitored for quality assurance	10-26 TK/BM		RR
Patients will be contacted by telephone to conduct informed consent.	12-26 TK/	BM	
Patients who provide their consent will complete the interview	13-26 TK/	BM	
Interview Data Entry De-Identification and Transfer			
Data entry and quality control measures will be ongoing at the VA	12-27 TK/	BM	
Data will be de-identified	13-27 TK/	BM	
Data will be transferred to NERI	26-27		RR
PHASE III – DATA ANALYSIS & REPORTS			
Conduct Data Analysis			
Analyses will be conducted to address the Specific Aims of the Registry	24-36		RR
Reports and Publication	24-36 TK/BM		RR
Continued Abstraction of Medical Records			
Perform abstraction periodically of VA in/outpatient electronic medical records for PTSD registrants who have return in/outpatient visits to VA medical centers	24-36 TK/BM		RR
Prepare PTSD Database for Future Use			
PTSD Registry database of 1200 OIF/OEF veterans will be prepared for potential sharing as a public dataset	34-36 TK/BM		RR